EFFICACY REVIEW

Premise Foam

Date:	04/15/04
Branch Supervisor:	Meredith Laws
Team Reviewer:	Dani Daniel
Efficacy Reviewer:	Joanne S. Edwards, MS Entomologist Joanne S Edwards 4/15/04
Secondary Efficacy Reviewer:	Kable Davis, MS Entomologist 4/15/04
EPA File Symbol:	432-RGOR
Case Number:	071303
DP Barcode:	D296866
Pest:	Termites
Formulation:	Imidacloprid.....0.05%
Chemical:	Imidacloprid 1-[(6-Chloro-3-pyridinyl)methyl]-N nitro-2-imidazolidinimine
Shaughnessy Number:	XXXXXX
Purpose:	Request is to review data to support a foam product
MRID:	46118903. Performance Data: Laboratory Studies of the Efficacy of Premise Foam. Guideline No. 810.3600. B. L. Reid. 2003. Study Number USA-F-052703. Bayer Environmental Science, Montvale, N.J.
GLP:	Study does not meet the requirements of GLP as per 40 CFR Part 160

BACKGROUND:

Registrant has submitted an application for a new product which combines imidacloprid (0.05%) and a foaming agent in a self-pressurized container. The product is to be used by pest management professionals as a supplement to kill subterranean termites that are found above ground.

The label states "Do not use this product as the sole source of control for active, structural infestations by subterranean termites; it is not a substitute for mechanical alteration, soil or foundation treatments. For active, structural infestations by subterranean termites, this product can only be used to supplement a soil-applied termiticide (e.g., Premise Insecticide), a termite bait system, or other product registered as a sole source for termite control. This product is intended as a supplemental tool to kill subterranean termites that are found in above ground and other locations."

Current Premise termiticide labeling contain directions for use for mixing imidacloprid with a foaming agent. These foam applications are applied (either alone or in combination with liquid solution) to difficult areas *e.g.*, wall voids, beneath and inside of masonry elements areas, into drywood termite galleries, where temporary expansion properties of foam allow for greater distribution of the insecticide.

The proposed product is intended to simplify applications. The directions for use on the draft label state the self-pressurized container dispenses Premise foam at a rate of approximately 5 ml (0.2 fl oz.) liquid formulation (approximately 0.2 L or 50 cubic inches of expanded foam) per second. The application tip is to be held firmly against the injection point for a full five seconds after releasing the dispenser trigger to minimize run-off.

REVIEW OF DATA:

> 46118903. Performance Data: Laboratory Studies of the Efficacy of Premise Foam. Guideline No. 810.3600. B. L. Reid. 2003. Study Number USA-F-052703. Bayer Environmental Science, Montvale, N.J.

Laboratory bioassay studies were conducted at four different locations (Bayer Vero Beach laboratories, U. Florida, Clemson U. and U. Georgia) using two different species of termites, *Reticulitermes flavipes* and *Coptotermes formosanus*. There was a total of eight distinct trials, each measuring termite knock-down. In addition, there was one residual efficacy test conducted at the Vero beach lab.

The basic methodology consisted of using a white pine board (ca 15 X 15 cm) scarified with saw cuts to simulate termite galleries, on top of which was placed another white pine board, which contained a large hole (made for termite entry) and another small hole (for foam injection). The

boards were held together using rubber bands or other type fasteners.

A microcolony of termites (up to about 2,000) was then placed in a 15-cm plastic petri dish containing a cardboard disk or pine block (1/1/2 inch) on the bottom of the dish. This microcolony was placed on top of the white pine board containing the large hole (to allow access from the petri dish into the hollowed spaces in the simulated gallery.

The termites were allowed to acclimate, *i.e.*, move into the simulated galleries between the two pine boards, for one week. After that, the foam treatment was dispensed. An injection tip was placed into the smaller hole, and a 1 to 2 second application was made from the pre-pressurized container. Two weeks after application the test units were taken apart, and mortality observations were made.

For the residual test, the foam was applied to the simulated galleries, and then the treated boards were stored in the lab. Bioassay testing was performed similarly to the knockdown tests, except on boards that had been aged for 1-week, 1-,3-, 6-, 12-, and 24 -month time periods.
As part of test validation of study design for the lab bioassays, occupancy of the simulated gallery in the untreated, control blocks was made at study termination (three weeks from beginning of acclimation for the knockdown tests), and for the residual test, after two weeks, when the mortality readings were taken.

Reported results for the knockdown tests:

Reported Results:

Test Facility	Species	No Replicates	Termites/ test unit	Rates tested	Control Mortality	Mortality (Abbott's formula)
Vero Beach	*R. flavipes*	3	2,000	0.025% 0.05%	16.4%	100% 100%
"	*C. formosanus*	3	500	0.025% 0.05%	43%	100% 99%
U. Florida	*R. flavipes*	3	2,000	0.025% 0.05%	17.3%	100% 78.6%
"	"	3	2,000	0.025% 0.05%	22.2%	82.1% 97.9%
"	"	3	2,000	0.025% 0.05%	30.3%	97.7% 95.8%
Clemson U.	"	6	500	0.05%	15%	68.5%
U. Georgia	"	5	500	0.05%	16.4%	91.3%
"	"	2	2,000	0.05%	3.8%	94.4%

The results show high knockdown (generally greater than 90%). The author states that the difference between the observed mortality data and complete kill can largely be explained by the continued presence of termites in the micro-colony that seem to have not been exposed.

Reported results of the residual test conducted at the Vero Beach lab:

Age of Residual Deposit	Concentration (%)[1]	Control Mortality (%)	Corrected Mortality (%) (Abbott's)	Living in Gallery (%)
1-week	0 0.025 0.05	14.9	 88 81	85 1.1 0
1-month	0 0.025 0.05	19.9	 85 81	79.3 4.3 2.4
3-months	0 0.025 0.05	26.2	 84 64	72.3 0 24
6-months	0 0.025 0.05	42.2	 57 84	57.7 1.1 0
12-months	0 0.025 0.05	1.7	 53 82	98.2 32.9 4
24-months	0 0.025 0.05	16.7	 66 49	63.3 4.7 9.1
Mean (Over all intervals)	o 0.025 0.05	20.3	 72.2 73.5	76.1 7.2 6.8

[1] weight-to-weight concentration of imidacloprid in the liquid foam concentrate before it expands after application.

The data demonstrate residual activity of imidacloprid. The mean (over all aging intervals) for both the 0.025 and 0.05% concentrations was greater than 72%.

RECOMMENDATIONS:

The submitted laboratory bioassays demonstrate kill of the two species of subterranean termites by imadicloprid concentrations of 0.05% and 0.025%.

There is no objection to the proposed foam product on the basis that (1) registered imidacloprid termiticide products already bear directions for mixing the products with foam, and (2) most registered termiticide products bear directions for using foam as a supplemental tool for

delivering the insecticide into difficult areas.

However, the following label changes are needed:

1. The label must specify how many cubic feet the product will treat, *i.e.*, "This pressurized container treats XXX cubic feet."

2. The label must specify what the expansion ratio is (all termiticide labels that have directions for foam applications specify an expansion ratio).

3. In accordance with PR Notice 96-7, the label must bear a restriction:

"The volume and amount of active ingredient are essential to an effective treatment. In a complete termiticide application, no more than 25% can be comprised of foam application."

(Note to PM: With the exception of the Premise conventional termiticide labels, all other termiticide product labels bear a statement similar to **"Foam and liquid applications must be consistent with volume and active ingredient instructions in order to ensure proper application has been made. The volume and amount of active ingredient are essential to an effective treatment. At least 75% of the gallons of product XX must be applied as a typical liquid treatment. The remaining 25% or less gallons is delivered tp appropriate locations using a foam application."** This language also needs to appear on the Premise termiticide product labels.)

4. The draft label states "For active, structural infestations by subterranean termites, this product can only be used to supplement a soil-applied termiticide (e.g., Premise Insecticide), a termite bait system, or other product registered as a sole source for termite control." This should be revised to read:

"For active, structural infestations by subterranean termites, this product can only be used to supplement a soil-applied termiticide, a termite bait system, or other product registered as a sole source for termite control."